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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.: 10/806,296  
Applicant: RABI, Jamie A.  
Filed: March 22, 2004  
TC/AU.: 1623  
Examiner: Unassigned

Confirmation No.: 1836

Docket No.: 06171.105107 IDX 1012B US  
Customer No.: 20786  
Title: Methods of Manufacture of 2-deoxy-beta-L-nucleosides

Commissioner for Patents  
P. O. Box 1450  
Alexandria, VA 22313-1450

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Sir:

The citation of information on the accompanying Form PTO-1449, "List of Art Cited by Applicant" is made pursuant to 37 C.F.R. §§ 1.56, 1.97, and 1.98. A copy of each reference is enclosed. The Examiner's attention is also drawn to U.S.S.N. 10/609,298. The citation of this information does not constitute an admission of priority or that any cited item is available as a reference, or a waiver of any right the applicant may have under applicable statutes, Rules of Practice in patent cases, or otherwise.

Applicants do not believe any fees are due because this paper is submitted before the mailing of a first Office action on the merits, as under 37 C.F.R. § 1.97(b)(3). However, the Commissioner is hereby authorized to charge any fees due or credit any overpayment to Deposit Account No. 11-0980.

Respectfully submitted,

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CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on September 10, 2004.

*Brent R. Bellows*  
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Substitute for form 1449A/PTO

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet

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of

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*Complete if Known*

Application Number	10/806,296
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First Named Inventor	Rabi, J.A.
Group Art Unit	1623
Examiner Name	Unassigned
Attorney Docket Number	06171.105107 IDX 1012B US

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## U.S. PATENT DOCUMENTS

Examiner Initials *	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages/Relevant Figures Appear
		Number	Kind Code (if known)			
AA	3,891,623	A		Vorbruggen <i>et al.</i>	06-24-1975	
AB	4,754,026	A		Kawada <i>et al.</i>	06-28-1988	
AC	4,957,924	A		Beauchamp	09-18-1990	
AD	5,144,018	A		Kuzuhara <i>et al.</i>	09-01-1992	
AE	5,565,438	A		Chu <i>et al.</i>	10-15-1996	
AF	5,567,688	A		Chu <i>et al.</i>	10-23-1996	
AG	5,587,362	A		Chu <i>et al.</i>	12-24-1996	
AH	6,153,594	A		Børretzen <i>et al.</i>	11-28-2000	
AI	6,248,878	B1		Matulic-Adamic <i>et al.</i>	06-19-2001	
AJ	6,271,212	B1		Chu <i>et al.</i>	08-07-2001	
AK	6,395,716	B1		Gosselin <i>et al.</i>	05-28-2002	
AL	6,444,652	B1		Gosselin <i>et al.</i>	09-03-2002	
AM	2003-0050229	A1		Sommadossi <i>et al.</i>	03-13-2003	
AN	6,566,344	B1		Gosselin <i>et al.</i>	05-20-2003	
AO	6,569,837	B1		Gosselin <i>et al.</i>	05-27-2003	
AP	2003-0083306	A1		Imbach <i>et al.</i>	05-01-2003	
AQ	2004-0006002	A1		Sommadossi <i>et al.</i>	01-08-2004	

## FOREIGN PATENT DOCUMENTS

Examiner Initials *	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages/ Relevant Figures Appear	T <sup>6</sup>
		Office <sup>3</sup>	Number	Kind Code <sup>2</sup> (if known)				
	AR	DD	0,140,254	Z	Akad. Wissenschaft der DDR Zentralinstitut für Molekularbiologie	02-20-1980		
	AS	DE	42 24 737	A1	Prof. Dr. Herbert Schott	02-03-1994		
	AT	EP	0 352 248	A1	Johansson <i>et al.</i>	01-24-1990		
	AU	JP	62-93645	A	Jpn. Kokai Tokkyo Koho	10-21-1994		translation
	AV	WO	95/07287	A1	CNRS	03-16-1995		
	AW	WO	96/11204.	A1	Max Delbrück Centr. Mol. Med.	04-18-1996		translation
	AX	WO	96/13512	A2	Genencor Int'l; Lipitek	05-09-1996		
	AY	WO	96/40164	A1	Emory U.; UAB Res. Found.; CNRS	12-19-1996		
	AZ	WO	00/09531	A2	Novirio Pharm. [Idenix]; CNRS	02-24-2000		
	AAA	WO	01/90121	A2	Novirio [Idenix]; Univ.... Cagliari	11-29-2000		
	AAB	WO	01/96353	A2	Novirio Pharm. [Idenix]; C.N.R.S.	21-20-2001		

Examiner Signature		Date Considered
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Substitute for form 1449A/PTO				<i>Complete if Known</i>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(use as many sheets as necessary)</i>				Application Number	<b>10/806,296</b>
Sheet	<b>2</b>	of	<b>3</b>	Filing Date	<b>March 22, 2004</b>
				First Named Inventor	<b>Rabi, J.A.</b>
				Group Art Unit	<b>1623</b>
				Examiner Name	<b>Unassigned</b>
				Attorney Docket Number	<b>06171.105107 IDX 1012B US</b>

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**OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>
	BA	BENZARIA, S., <i>et al.</i> , "Synthesis of potential prodrugs of b-4-L-dC, a potent and selective anti-HBV agent," <i>Antiviral Res.</i> , 50:A79 (2001). [Abstract no. 137].	
	BB	BLOCH, A., <i>et al.</i> , "The Role Of The 5'-Hydroxyl Group Of Adenosine In Determining Substrate Specificity For Adenosine Deaminase," <i>J. Med. Chem.</i> , 10(5):908-12 (September 1967).	
	BC	BRYANT, M.L., <i>et al.</i> , "Antiviral L-nucleosides specific for hepatitis B virus infection," <i>Antimicrob. Agents Chemother.</i> , 45(1):229-235 (January 2001).	
	BD	BUDAVERI, <i>et al.</i> , <i>The Merck Index</i> , 12th Edition, Entry no. 10039, p. 10044.	
	BE	CAVELIER, F., <i>et al.</i> , "Studies of selective Boc removal in the presence of silyl ethers," <i>Tetrahedron Letters</i> , 37:5131-5134 (1996).	
	BF	CRETTON-SCOTT, E., <i>et al.</i> , "Pharmacokinetics of β-L-2'-deoxycytidine prodrugs in monkeys," <i>Antiviral Res.</i> , 50:A44 (2001) [Abstract no. 16].	
	BG	DAVISON, V.J., <i>et al.</i> , "Synthesis of Nucleotide 5'-Diphosphates from 5'-O-Tosyl Nucleosides," <i>J. Org. Chem.</i> , 52(9):1794-1801 (1987).	
	BH	FOX, J.J., <i>et al.</i> , "Thiolation of nucleosides. II. Synthesis of 5-methyl-2'-deoxycytidine and related pyrimidine nucleosides," <i>J. Am. Chem. Soc.</i> , 81:178-187 (1959).	
	BI	HOARD, D.E., <i>et al.</i> , "Conversion of Mono- and Oligodeoxyribonucleotides to 5'-Triphosphates," <i>J. Am. Chem. Soc.</i> , 87(8):1785-1788 (April 20, 1965).	
	BJ	HOLY, A., "Nucleic Acid Components and Their Analogs. CLIII. Preparation of 2'-deoxy-L-Ribonucleosides of the Pyrimidine Series," <i>Collect. Czech. Chem. Commun.</i> , 37(12):4072-4087 (1972).	
	BK	IMAI, K., <i>et al.</i> , "Studies on Phosphorylation. IV. Selective Phosphorylation of the Primary Hydroxyl Group in Nucleosides," <i>J. Org. Chem.</i> , 34(6):1547-1550 (June 1969).	
	BL	KANEKO, M., <i>et al.</i> , "A convenient synthesis of cytosine nucleosides," <i>Chem. Pharm. Bull.</i> , 20:1050-1053 (1972).	
	BM	KERR, S.G., <i>et al.</i> , "N4-(dialkylamino)methylene derivatives of 2'-deoxycytidine and arabinocytidine: physicochemical studies for potential prodrug applications," <i>J. Pharm. Sci.</i> , 83(4):582-586 (April 1994).	
	BN	LIN, T.-S., <i>et al.</i> , "Synthesis of Several Pyrimidine L-Nucleoside Analogues as Potential Antiviral Agents," <i>Tetrahedron Letters</i> , 51(4):1055-1068 (1995).	
	BO	LUH, T.-Y., <i>et al.</i> , "A convenient method for the selective esterification of amino-alcohols," <i>Synthetic Communications</i> , 8(5):327-333 (1978).	
	BP	MAGA, Giovanni, <i>et al.</i> , "Lack of stereospecificity of suis pseudorabies virus thymidine kinase," <i>Biochem. J.</i> , 294(2):381-385 (1993).	
	BQ	McCORMICK, J., <i>et al.</i> , "Structure and total synthesis of HF-7, a neuroactive glyconucleoside disulfate from the funnel-web spider <i>Hololena curta</i> ," <i>J. Am. Chem. Soc.</i> , 121(24):5661-5664 (1999).	

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	CA	PIERRA, C., <i>et al.</i> , "Comparative studies of selected potential prodrugs of $\beta$ -L-dC, a potent and selective anti-HBV agent," <i>Antiviral Res.</i> , 50:A79 (2001). [Abstract no. 138].			
	CB	STANDRING, D.N., <i>et al.</i> , "Antiviral beta-L-nucleosides specific for hepatitis B virus infection," <i>Antiviral Chem. &amp; Chemother.</i> , 12 (Suppl. 1):119-129 (2001).			
	CC	TANG, X.-Q., <i>et al.</i> , "2'-C-Branched ribonucleosides: Synthesis of the phosphoramidite derivatives of 2'-C-b-methylcytidine and their incorporation into oligonucleotides," <i>J. Org. Chem.</i> , 64(3):747-754 (1999).			
	CD	TYRSTED, G., <i>et al.</i> , "Inhibition of the synthesis of 5-phosphoribosyl-1-pyrophosphate by 3'-deoxyadenosine and structurally related nucleoside analogs," <i>Biochim. Biophys. Acta.</i> , 155(2):619-622 (February 26, 1968).			
	CE	VERRI, A., <i>et al.</i> , "Lack of enantiospecificity of human 2'-deoxycytidine kinase: relevance for the activation of $\beta$ -L-deoxycytidine analogs as antineoplastic and antiviral agents," <i>Molecular Pharmacology</i> , 51(1):132-138 (January 1997).			
	CF	VERRI, A., <i>et al.</i> , "Relaxed Enantioselectivity of Human Mitochondrial Thymidine Kinase and Therapeutic Uses of L-Nucleoside Analogues," <i>Biochem. J.</i> , 328(1):317-320 (November 15, 1997).			
	CG	Von JANTA-LIPINSKI, M., <i>et al.</i> , "Newly Synthesized L-Enantiomers of 3'-Fluoro-Modified $\beta$ -2'-Deoxyribonucleoside 5'-Triphosphates Inhibit Hepatitis B DNA Polymerase but not the Five Cellular DNA Polymerases $\alpha$ , $\beta$ , $\gamma$ , $\delta$ , and $\epsilon$ Nor HIV-1 Reverse Transcriptase," <i>J. Medicinal Chemistry</i> , 41(12):2040-2046 (May 21, 1998).			
	CH	ZEDECK, M.S., <i>et al.</i> , "Inhibition of the steroid-induced synthesis of D5-3-ketosteroid isomerase in <i>Pseudomonas testosterone</i> by a new purine deoxyribonucleoside analog: 6-chloro-8-aza-9-cyclopentylpurine," <i>Mol. Pharmacol.</i> , 3(4):386-395 (1967).			
	CI	ZHANG, W., <i>et al.</i> , "Removal of silyl protecting groups from hydroxyl functions with ammonium fluoride in methanol," <i>Tetrahedron Letters</i> , 33:1177-1180 (1992).			

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